REMARKS

A. Status of the Claims

Claims 1, 5-12, and 14-41 are currently pending and are under examination. By the present amendment, claims 1, 22, 23, 27, 39, and 40 have been amended to more particularly define the Applicants' invention and to claim it with greater specificity. Claims 2-4 and 13 were previously canceled without prejudice. New claims 42-61 have been added. Claims amendments and new claims are supported by the specification and the original claims. No new matter have been added.

For example, a limitation "a pre-existing" referring to retinal detachment, was added to claims 1, 22, 23, 27, 39, and 40. This limitation is disclosed in Example 1 (paragraph [0075] on page 20, where retinal detachment was preliminarily created in rabbits' eyes, followed by the treatment using HDP-cCDV. Accordingly, retinal detachment had already been in existence when the treatment had commenced; hence, such retinal detachment was "pre-existing."

After the present amendment has been entered, claims 1, 5-12 and 14-61 will be pending and will be under consideration.

B. Rejections Under 35 U.S.C. § 112

Claims 1, 5-12, and 14-41 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention (the written description requirement) (item 4 on page 3 of the Office Action). These are new matter rejections.

The Examiner has stated that the limitations "eye trauma" and "scratching" recited in claims 1, 22, 23, and 25-27 are allegedly directed to new matter.

The rejection is traversed. With respect to "eye trauma" it was recited in the original claim 13. Since there is no dispute that the originally claims are the part of the application as filed, the term "eye trauma" is, therefore, supported and is not new matter.

With respect to the term "scratching," while the Applicants respectfully disagree that such a limitation constitutes any new matter, it is submitted that this limitation has been deleted by the current amendment, making the rejection moot.

In view of the foregoing, it is respectfully submitted that the rejections under 35 U.S.C. § 112 do not apply. Withdrawal of the rejections and reconsideration are respectfully requested.

C. Rejections Under 35 U.S.C. § 102 (a) and(b)

Claims 1, 5-12, 14,15 and 22-26 stand rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Cheng et al., *Investigative Ophthalmology & Visual Science*, Feb. 2002, vol. 43 ("Cheng I") (item 6 on pages 3-4 of the Office Action). In addition, claims 1, 5-12, 14,15 and 22-26 also stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Cheng et al., *Investigative Ophthalmology & Visual Science*, May 2000, vol. 41, No. 6 ("Cheng II") (item 8 on page 6 of the Office Action). These rejections are respectfully traversed because neither Cheng reference describes all the elements and limitations recited in claim 1, as amended.

Each of claims 1, 22, and 23, as amended, now include limitations requiring that the method be used for the treatment of "macular degeneration, eye trauma, a pre-existing retinal detachment, ocular proliferative or vascular diseases, or diseases of elevated intraocular pressure or inflammation." There is nothing in either Cheng I or Cheng II explicitly or inherently describing a method that includes such treatments. Both Cheng I and Cheng II teach only the methods for the treatment of viral retinitis (cytomegalovirus (CMV) infection of the retina) and are using for this purpose certain compounds, such as HDP-P-GCV (1-O-hexadecylpropanediol-3-phospho-ganciclavir).

The Examiner again emphasized that Cheng II mentions retinal detachment on page 1523. The Applicants had already explained and now respectfully re-iterate that this mentioning does not teach the treatment of retinal detachment. Cheng II discusses the difficulties inherent in surgical implantation of the sustained-release ganciclovir that was previously used to treat the viral infection and briefly mentions that one of such difficulties can be retinal detachment.

There is nothing in either Cheng reference explicitly or implicitly describing that the method of claim 1 can be used for the treatment of **pre-existing** retinal detachment, or any other recited condition, such as, macular degeneration, eye trauma, ocular proliferative or vascular diseases, or diseases of elevated intraocular pressure or inflammation. To state succinctly, Cheng I and II teach such methods of treatment of viral retinitis that would not cause retinal detachment due to scarring, or even will prevent such retinal detachment. The present claims are distinctly different and are directed to treatments of **already existing** retinal detachment.

With respect to the limitation "eye trauma" recited in claims 1, 22, and 23, the Examiner stated that retinitis can be characterized as one of the conditions of eye trauma (see, page 5, last three lines of the Office Action). It is not entirely clear to the Applicants what the basis for such a statement is. The Applicants respectfully request that the Examiner provide scientific or medical authority that allows him to arrive at this conclusion, with which the Applicants respectfully disagree.

Retinitis is not generally known to be related to eye trauma which is commonly understood as a mechanical injury to an eye, e.g., an injury caused by penetration of a sharp or blunt foreign object into the eye. Claims 1, 22 and 23 are directed to the treatment of such an injury, and have nothing to do with the treatment of retinitis. Cheng I and II discuss treatments of retinitis, but of course retinitis in Cheng I and II is of a viral origin and has no relation to eye injury. Thus, the teachings of Cheng I and II cannot be reasonably extended to the treatment of eye trauma.

Finally, it is a well established rule that a proper anticipation reference must be enabling. Indeed, for a prior art reference to be valid, the reference must place the invention in the possession of the public by providing an enabling disclosure of how to make and use the invention. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Neither Cheng I nor Cheng II would enable one skilled in the art to treat eye trauma or retinal detachment. The amount of disclosure that can be found in these references is absolutely minimal as far as the treatment of retinal detachment is concerned. There are no examples in Cheng I of Cheng II directed to the treatment of this condition. In addition, in Cheng I of Cheng II, there is no description whatsoever related to the methods of treatment of eye trauma.

Accordingly, it is submitted that one skilled in the art would not be able, after reviewing Cheng I and Cheng II, to practice this method, i.e., to treat the patients already suffering from retinal detachment or from eye trauma, without resorting to extensive and undue experimentation. Therefore, Cheng I and Cheng II are both non enabling and cannot be used for a rejection by anticipation.

Thus, neither Cheng reference discloses every element of claims 1, 22 or 23 as amended, and, therefore, neither is a proper anticipation reference, whether under 35 U.S.C. § 102 (a) or under 35 U.S.C. § 102 (b), making each of claims 1, 22, and 23, as amended, patentably distinguishable over both Cheng references. Each of claims 5-12, 14, 15 and 24 depends on claim 1, directly or indirectly, and is accordingly considered patentable for at least the same reason. Withdrawal of the rejection and reconsideration are respectfully requested.

D. Rejections Under 35 U.S.C. § 103 (a)

Claims 16-21 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Cheng I and Cheng II in view of U.S. Patent No. 6,120,751 to Unger ("Unger")

(item 11 on page 8 of the Office Action). In addition, claims 27-41 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Cheng I and Cheng II in view of U.S. Unger and further in view of Cundy et al., *Curr. Eye Res.*, vol. 15, pp. 569-576, 1996 ("Cundy") (item 13 on page 10 of the Office Action) and Hostetler et al. Antimicrob. Agents. Chemother., vol. 46, No. 8, pp. 2381-2386, August 2000. The Applicants assume that the last reference is item AE on the form PTO-1449 ("Biddle"). The rejection is respectfully traversed on the following grounds.

The *KSR* standard that has to be satisfied in order to make a valid rejection based on a *prima facie* case of obviousness was discussed in a response to a previous Office Action. It is submitted that this standard has not been met by the Examiner.

More specifically, neither Cheng reference discloses or suggests the treatment of particular diseases and disorders recited in claim 1, as discussed above. To re-iterate neither Cheng reference discloses or suggests the treatment of macular degeneration, eye trauma, a pre-existing retinal detachment ocular proliferative or vascular diseases, or diseases of elevated intraocular pressure or inflammation. Unger fails to eliminate this deficiency. Unger only teaches compositions for targeted drug delivery. There is nothing in Unger even remotely suggesting the use of such compositions for the treatment of the above-mentioned ocular diseases and disorders.

It is, therefore, submitted that there is no evidence suggesting a skilled artisan knowing the teachings of Cheng I and II and Unger, would without more, be motivated to make a modification described by the Examiner by combining Cheng I and/or II with Unger. Nor is there anything that would suggest a reasonable expectation of success as a result of such modification. Accordingly, the first two prongs of *KSR* test have not been satisfied.

Turning now to the second obviousness rejection, neither Cheng reference discloses or suggests the treatment of particular diseases and disorders recited in claim 27, as discussed above. More specifically, both Cheng I and Cheng II are silent with

regard to the treatment of macular degeneration, eye trauma, or a pre-existing retinal detachment recited in claim 27. Cundy teaches only the methods related to the treatment of viral CMV retinitis; Biddle discusses the same, i.e., describing derivatives of cidofovir and cyclic cidofovir as antiviral agents that are effective against the CMV virus.

In effect, Cundy and/or Biddle merely supplement the teachings of Cheng I and/or Cheng II by providing more details related to the treatment of viral retinitis. Since, as shown above, treating pre-exiting retinal detachment and eye trauma is distinct from treating CMV retinitis. Therefore, Cundy and/or Biddle fail to cure the deficiencies of Cheng I and/or Cheng II.

Indeed, even if Cundy or Biddle or a combination thereof is/are combined with Cheng I and/or Cheng II, as suggested by the Examiner, the combination would still fail to teach or fairly suggest all the limitations of claim 27, as amended. Thus, at least one of the requirements of the KSR test has not been satisfied, which requires that a combination of references has to teach or suggest all of the recited claim limitations.

In view of the foregoing, it is respectfully submitted claim 1 is patentably distinguishable over Cheng I and II in view of Unger, and claim 27 is patentably distinguishable over Cheng I and II in view of Cundy and/or Biddle. Each of claims 16-21 and 28-41 depends, directly or indirectly, on either claim 1 or claim 27, and is allowable for at least the same reason. Reconsideration and withdrawal of the rejection are respectfully requested.

E. <u>New Claims</u>

By the present amendment, the Applicant added new claims 42-61. These claims are both novel and non-obvious over the cited art. Indeed, each of these claims is directed to the methods of treatment of macular degeneration, ocular proliferative or vascular diseases, or diseases of elevated intraocular pressure or inflammation. Please

note that neither eye trauma nor retinal detachment is recited. None of the references provided by the Examiner teach or suggest such treatments.

CONCLUSION

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

No fee is deemed necessary with the filing of this response. However, if any fees are due, the Commissioner is hereby authorized to charge any fees, or make any credits, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,

Date: January 17, 2008

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